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scientific device manufacturer, inc.

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## **SUMMARY OF SAFETY AND AFFECTIVENESS**

### **SDM CONTROL SYRINGES**

#### **510(k) Premarket Notification**

**Trade Name:** SDM Control Syringes

**Generic Name:** High Pressure Syringes

**Manufacturer:** Scientific Device Manufacturer, Inc.  
999 Andersen Drive, Suite 110  
San Rafael, CA 94901  
Establishment Registration Number: TBD

#### **Classification:**

In preparation of this PreMarket Notification, it was determined that devices of this generic type have been previously classified as Class II devices. No performance standards have yet been established for these products.

#### **Product Description:**

The SDM Control Syringes consist of visibly clear high strength polycarbonate barrels, an elastomeric piston, and a high strength polymeric plunger terminating in a palm plate. The device is modeled in the European style in regard to the finger grips and palm plate. Each barrel is marked to 10cc's of volume in increments of 0.2cc and is very lightly coated with a medical grade silicone oil to enhance smootheness of operation. Two models will be available, one having a 0.5cc reservoir of internal volume remaining in the fully inserted position. The other model will leave no reservoir following full travel of plunger to the bottom of the barrel. These devices will be supplied single packaged and sterile. Packaging will consist of standard Tyvek/Poly pouches.



**Intended Use:**

This device is intended for hand injection of contrast media during angiography.

**Rationale for Substantial Equivalence:**

Scientific Device Manufacturer's Control Syringes are substantially equivalent to currently marketed "Control" and "Angiographic" syringes with regard to intended use, materials, and design. Predicate devices include those made by Medex, Namic, Becton Dickinson and Merit. No significant changes or modifications were made from those predicate devices. SDM therefore posits that its devices are equivalent in safety and effectiveness to those devices.

**Biocompatibility Evaluations:**

Materials used in Scientific Device Manufacturer's Control Syringes were chosen to be generically of the same type and grade as those present in the substantially equivalent devices. Testing performed by SDM for this externally communicating device (blood path indirect) shows this device to be biocompatible per requirements of ISO Standard 109993, Part I.

**Summary:**

Based upon the product description, its intended use, and comparative features of predicate devices, the Scientific Device Manufacturer's Control Syringes are substantially equivalent to other high pressure syringes currently approved for use.

Richard C. Ball

Vice President Regulatory Affairs and Quality Assurance